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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/512,024 | 05/09/2005 | Abdullah Ibrahim Haj-Yehia | YISS2000100 | 2208 |
| 25226 | 7590 | 09/28/2006 | EXAMINER | |
| MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | FREISTEIN, ANDREW B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/512,024

Applicant(s)

HAJ-YEHIA, ABDULLAH IBRAHIM

Examiner

Andrew B. Freistein

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-38 are currently pending in the instant application.

Priority

This application is a 371 of PCT/IL03/00312, filed 04/15/2003, which claims benefit of US provisional application no. 60/374,173, filed 04/19/2002.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-38 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

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"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

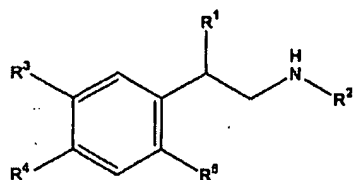
(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

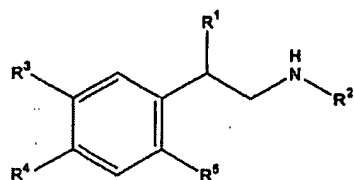
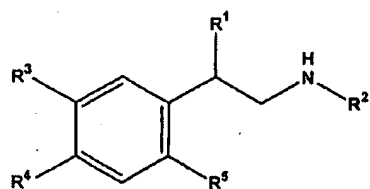
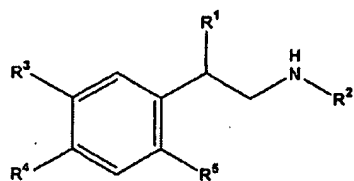
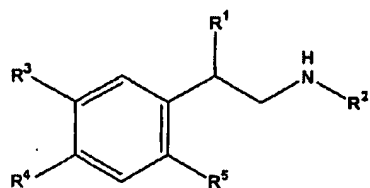
Due to numerous and widely divergent variables in the compound of Formula (I), for example: R^1 , R^2 , R^3 , R^4 and R^5 , a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I: Claims 1-9 and 26-29 (in part), drawn to products of formula (1),



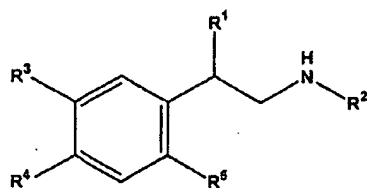
, wherein R^1 is SNO; R^2 is pyrrolidine; R^3 and R^4 together with the phenyl ring form an isoindole; and R^5 is H or alkyl.

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Group II: Claims 1-9 and 26-29 (in part), drawn to products of formula (1),, wherein R^1 is SNO; R^2 is a straight or branched alkyl chain; R^3 and R^4 together with the phenyl ring form an isoindole; and R^5 is H or alkyl.**Group III:** Claims 1-9 and 26-29 (in part), drawn to products of formula (1),, wherein R^1 is SNO; R^2 is piperidine; R^3 and R^4 together withthe phenyl ring form an isoindole; and R^5 is H or alkyl.**Group IV:** Claims 1-9 and 26-29 (in part), drawn to products of formula (1),, wherein R^1 is ONO_2 ; R^2 is ; n is 1-15; R^3 is NHCHO ; R^4 OH; and R^5 is H or alkyl.**Group V:** Claims 1-9 and 26-29 (in part), drawn to products of formula (1),, wherein R^1 is ONO_2 ; R^2 is ; n is 1-15; R^3 and R^4 together with form a 1,3-dioxane; and R^5 is H or alkyl.

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Group VI: Claims 1-9 and 26-29 (in part), drawn to products of formula (1),



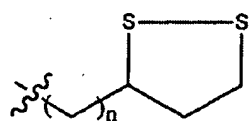
, wherein R¹ is OH; R² is cyclohexane; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group VII: Claims 10-14, drawn to a process of preparing a compound of formula (1), wherein R¹ is SNO; R² is pyrrolidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group VIII: Claims 10-14, drawn to a process of preparing a compound of formula (1), wherein R¹ is SNO; R² is a straight or branched alkyl chain; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group IX: Claims 10-14, drawn to a process of preparing a compound of formula (1), wherein R¹ is SNO; R² is piperidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

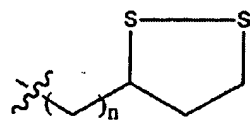
Group X: Claims 16-25 and 34-36, drawn to a method of treating a respiratory disorder comprising administering a compound of formula (1), wherein R¹ is ONO₂; R² is



; n is 1-15; R³ is NHCHO; R⁴ OH; and R⁵ is H or alkyl.

Group XI: Claims 16-25 and 34-36, drawn to a method of treating a respiratory disorder comprising administering a compound of formula (1), wherein R¹ is ONO₂; R² is

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; n is 1-15; R³ and R⁴ together with form a 1,3-dioxane; and R⁵ is H or alkyl.

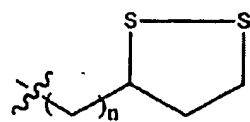
Group XII: Claims 16-25 and 34-36, drawn to a method of treating a respiratory disorder comprising administering a compound of formula (1), wherein R¹ is OH; R² is cyclohexane; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XIII: Claim 30, drawn to a pharmaceutical composition for use in treatment comprising a compound of formula (1), wherein R¹ is OH; R² is cyclohexane; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XIV: Claim 30, drawn to a pharmaceutical composition for use in treatment comprising a compound of formula (1), wherein R¹ is SNO; R² is pyrrolidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XV: Claim 30, drawn to a pharmaceutical composition for use in treatment comprising a compound of formula (1), wherein R¹ is SNO; R² is a straight or branched alkyl chain; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XVI: Claim 37, drawn to an inhalation device for administering a multifunctional B-agonist compound of formula (1), wherein R¹ is ONO₂; R² is



; n is 1-15; R³ is NHCHO; R⁴ OH; and R⁵ is H or alkyl.

Group XVII: Claim 37, drawn to an inhalation device for administering a multifunctional B-agonist compound of formula (1), wherein R¹ is SNO; R² is piperidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XVIII: Claim 37, drawn to an inhalation device for administering a multifunctional B-agonist compound of formula (1), wherein R¹ is SNO; R² is a straight or branched alkyl chain; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XIX: Claim 38, drawn to a kit comprising an inhalation device comprising a compound of formula (1), wherein R¹ is SNO; R² is pyrrolidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

Group XX: Claim 38, drawn to a kit comprising an inhalation device comprising a compound of formula (1), wherein R¹ is SNO; R² is piperidine; R³ and R⁴ together with the phenyl ring form an isoindole; and R⁵ is H or alkyl.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. As stated above, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter claimed in this application.

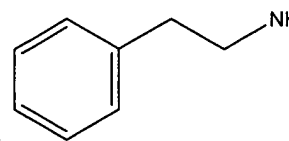
The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-XX** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical

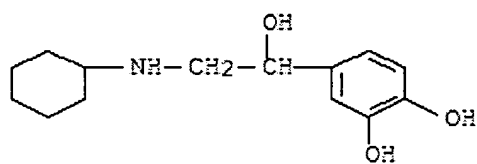
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features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-XX** is



This technical feature is not a special technical feature, because it fails to define a contribution over the prior art. For example, see Johansson et al., "b2-Adrenoceptor selectivity in four series of b-adrenoceptor agonists," European Journal of Pharmacology, Vol. 130(1-2), pp. 97-103 (1986), which discloses the compound:



(see p. 98, Table 1, Series II, KWD 2314(3)).

Therefore, claims 1-38 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-XX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

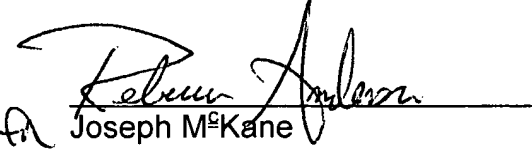
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626


Joseph M^cKane
Supervisory Patent Examiner, AU 1626
Date: September 14, 2006